REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated November 29, 2001 are respectfully requested. Applicants petition the Commissioner for a 2-month extension of time. A separate petition accompanies this amendment.

Applicants thank the Examiner for an indication that claim 14 is in condition for allowance and that claims 4-5, 32, 33, 42-49 and 52-74 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claim.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned **"Version With Markings to Show Changes Made."**

I. Amendments

A. In the Specification:

The specification is amended to correct obvious typographical errors and for correct grammar.

B. In the Claims:

Claims 2-4, 8, 13, 15-21, 26-27, 30, 33, 35-41, 51, 75-78, and 81-82 stand cancelled.

Claim 1 is amended to recite that the sensor array is configured to measure a spectral profile of at least one portion of the tissue site. Claim 1 is further amended for clarity. Support for these amendments can be found in original claims 1 and 4.

Claim 5 is amended to depend from claim 1.

Claims 6-7, 10, 12, 14, 22, and 31 are amended for clarity.

Claim 11 is amended to clarify that the logic resources are configured to interface with the display device. Support for this amendment can be found on page 24, lines 20-28.

Claims 32, 56, 64, and 67 are amended for proper markush format.

Claim 42 is rewritten in independent format. Claim 42 is further amended for proper markush format.

Claim 50 is amended to clarify at least one of the elongated delivery device or at least one of the plurality of resilient members is adapted for fluid delivery therethrough to an infusion port. Support for this amendment can be found on page 36, lines 25-28 and on page 37, lines 9-10.

Claim 52 is rewritten in independent format.

Claim 57 is amended to clarify that the marking agent is reactive to a delivery of energy.

Claim 79 is amended to depend from claim 1. Claim 79 is additionally amended for clarity.

Claim 80 is amended to clarify that the second advancement member is configured to advance a second resilient member.

By these amendments, no new subject matter has been added.

II Rejection under 35 U.S.C. §102

Claims 1-3, 6-13, 15-31, 35-41, 50, 51, and 75-82 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Gough *et al.* (U.S. Patent No. 5,735,847). These rejections are respectfully traversed.

A. The Present Invention

The present invention describes a tissue biopsy and treatment apparatus for detecting and treating tumors. The apparatus comprises an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue, and a sensor array deployable from the elongated delivery device. The sensor array includes a plurality of resilient members each having a tissue piercing distal portion, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state. At least one of the plurality of resilient members includes a sensor, the sensor array has a geometric configuration adapted to volumetrically sample tissue at a tissue site or identify tissue at a tissue site. At least some of the resilient

members are electrodes which can be coupled to an RF energy source for ablating tissue when electrical energy is supplied to the electrodes from the source. The sensor array is configured to measure a spectral profile of at least one portion of the tissue site.

B. The Prior Art

GOUGH ET AL. describe a multiple antenna ablation device. The multiple antenna device includes a primary antenna with a lumen and a longitudinal axis and a distal end sufficiently sharp to pierce tissue, and a secondary antenna at least partially positioned in the secondary antenna. The secondary antenna includes a distal portion configured to be deployed from the lumen in a lateral direction relative to the longitudinal axis, wherein at least a part of a deployed secondary antenna distal portion has at least one radius of curvature. The device is configured to be coupled to an energy source. The device further includes a cooling element coupled to the primary antenna.

C. Analysis

Gough *et al.* fail to teach that the sensor array is configured to measure a spectral profile of at least one portion of the tissue site. Nowhere do Gough et al. make any mention of measuring a spectral profile.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

III. Rejections under 35 U.S.C. §103

Claims 73 and 74 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.*

A. The Present Invention

The present invention is described above.

B. The Prior Art

GOUGH ET AL. is described above.

C. Analysis

If an independent claim is non-obvious under 35 U.S.C. §103 then any claim depending therefrom is non-obvious. M.P.E.P. §2143.03. The rejection of dependent claims 73 and 74 relies on Gough *et al.*, the deficiencies of which are discussed above. Nor do Gough *et al.* provide motivation for measuring a spectral profile of at least one portion of a tissue site.

Accordingly, dependent claims 73 and 74 patentably define over the teaching of Gough *et* al. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for Allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

Jacqueline F. Mahoney

Date: April 29, 2003

Jacqueline F. Mahoney
Registration No. 48,390

Correspondence Address:
Customer No. 22918
(650) 838-4300

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

On page 4, please replace the paragraph starting on line 5 with the following:

Yet another embodiment of the invention includes a method for tumor detection, wherein a primary optically labeled marker or antibody is infused into a patient or injected into a target tissue or organ site containing a tumor and specifically binds to a marker produced by or associated with a tumor. The target tissue or organ site is scanned with a biopsy ablation apparatus including a sensor array and the binding sites of the labeled marker antibody are located by detecting elevated levels of optical label signal intensity at such sites with the sensor array. This information can be digitally stored and displayed on a monitor device to accurately position the biopsy ablation apparatus within the tumor s to deliver energy to necrose or ablate the tumor resulting in an ablation volume. A second marker which binds or reacts with necrosed tumor tissue can infused or injected into the tumor site before, during or after the delivery of ablating energy. The sensor array is utilized to detect the signal from the second marker ablation volume and this signal digitally stored and superimpose[dly] the display over tumor volume image so as to determine the size of the ablation volume relative to the tumor volume. This embodiment provides two key benefit to the physician: (i) visual confirmation that the tumor has been completely ablated/necrosed, (ii) selective control over [control] the amount of healthy tissue margin that is ablated beyond the tumor volume to improve clinical outcomes of the procedure.

On page 16, please replace the paragraph starting on line 11 with the following:

Referring back to Figure 4, emitting member 22me can include an integral light source 17 such as an LED or a diode laser or alternatively can be optically coupled to an external light source 17 which in various embodiments, can be configured to emit light at multiple wavelengths and over a range of wavelengths including, but limited to the range of 300 to 850 nm, a more preferred range of 450 to 850 nm with specific

embodiments in the UV and infrared ranges. In an embodiment light source 17 can be a monochrometer known in the art. Examples of monochrometers include single crystal, double crystal and surface normal reflection monochrometers as well as models manufactured by Macken Instruments Inc. (Santa Rosa, Calif.). In other embodiments, light source 17 can be a white light source, a xenon bulb, an LED or a coherent light source such as a laser configured to emit probe beam 22ib. Examples of lasers include, but are not limited to, YAG lasers, Nd:YAG lasers, CO2 lasers, infrared lasers, argon lasers, tunable dye lasers and copper vapor lasers. Referring now to Figure 10, laser device 17 can include multiple beams at different wavelengths including a first 22ib' and a second beam 22ib" having a first and second wavelength 7' and 7" wavelength. Examples of multiple wavelength emitting lasers include CO_2 lasers and argon-pumped tunable dye lasers. The use of multiple and/or a broad spectrum of wavelengths 7 provides the benefit of increased tissue or tissue chromophore specificity and hence increased predictive power (e.g. statistical confidence) of associated tissue identification algorithms described herein. The use of laser light source 17 with multiple beams and wavelengths can also be configured to determine the deployment distance of one or more members 18, 18e using laser range finding methods known in the art.

On page 25, please replace the paragraph starting on line 10 with the following:

In addition to identifying tissue types, apparatus 10 and sensor arrays 22a can also be employed to monitor the progression of an ablative procedure including the progression of an ablation volume 5av resulting from the delivery of energy to target tissue volume 5. Referring now to Figures 14a and 14b, emitters 22a and detectors 22md can be configured to monitor the moving boundary layer of cell necrosis 55 and/or thermal fronts 55t of a developing ablation volume 5av. This can be achieved by monitoring for the presence of metabolic chromophores 33 or markers 9 indicative of cell necrosis or ablation described herein. The spectral signal intensity 19s (at one or more wave lengths 7) for a volume of tissue between one or more emitters 22me and detector 22md can be monitored over time. An endpoint for ablation can be determined based on either a selectable threshold value 19ts of signal 19s or an inflection point or change in slope 19ds (e.g. a derivative) of curve 19s or a combination of both. In an

embodiment signal 19s can comprise the subtraction of a baseline (or reference) spectral measurement 19sbl of a nearby, but non-ablated tissue volume, from a real time measurement 19srt of the target tissue volume during the time course of ablation. This compensates for any signal or tissue hysteresis over time. Signal/curve 19s can include both spectral, thermal and impedance measurements. Values for 19ts and 19s can be input and stored in logic resource 19lr coupled to spectrophotometer 19 or incorporated into an electronic algorithm controlling the delivery of energy which can be stored in a controller or processor 338 coupled to power supply 20.

On page 26, please replace the paragraph starting on line 5 with the following:

In related embodiments, sensor array 22a can be configured to monitor for any number of indicators of cell necrosis that can be utilized to qualitatively or quantitatively assess the progress of an ablation and determine a meaningful clinical endpoint. Such indicators and associated monitoring and endpoint methods include, but are not limited to, the following: monitoring interstitial moisture or hydration levels (these would be expected to go up as cells lyse and then go down as fluid is boiled or evaporated) and utilizing a decrease below a lower threshold as an endpoint; monitoring interstitial electrolyte concentrations (which increase with cell lysis); monitoring for interstitial fatty acid and amino acid concentrations (which would increase with cell lysis and then decrease due thermal degradation); monitoring for the increase or decrease of marker compounds 9; monitoring impedance; monitoring tissue temperature changes using near-infrared or thermocouple measurements; monitoring tissue color changes (e.g. red to white), monitoring for protein or collagen denaturization; monitoring for the release of DNA, gene fragments, DNA fragments or degraded DNA; monitoring for the release of RNA, RNA fragments or RNA fragments; monitoring for changes in tissue oxygenation in the form of PO_2 or oxyhemoglobin; monitoring for changes in PCO_2; monitoring for decrease or cessation of blood flow rates (an indication of tissue coagulation) using optical (e.g. laser Doppler) or acoustical (e.g. doppler ultrasound) sensors and monitoring for the presence of vapor bubbles and rate of vapor bubble formation. In a specific embodiment, sensor array is configured to monitor the rate of vapor bubble formation (using either optical and/or acoustic/ultrasound sensors 22) and as an

indicator of both rate of ablation and also a treatment endpoint. A treatment control and endpoint algorithm in module 19a employing this method would initially look for an increase in bubble rate formation and then a decrease below a set threshold as the endpoint. Other related embodiments can be configured to monitor for various cellular functions indicative of injury or necrosis.

On page 36, please replace the paragraph starting on line 4 with the following:

Referring now to Figures 25 through 28 in various embodiments one or more electrodes 18e can be covered by an insulative layer 36 so as to have an exterior surface that is wholly or partially insulated and provides a non-insulated area which is an energy delivery surface 18eds. In an embodiment shown in Figure 25, insulative layer 36 can comprise a sleeve that can be fixed or slidably positioned along the length of electrode 18e to vary and control the length 36' of energy delivery surface 18eds. Suitable material for insulative layer 36 include polyimide and [flouro-carbon]fluorocarbon polymers such as TEFLON.

In the Claims:

1. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members each having a tissue piercing distal portion, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including [at least one of] a sensor[, a tissue piercing distal end or a lumen], the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site or identify tissue at a tissue site; [and

at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device]at least some of said

resilient members being electrodes which can be coupled to an RF energy source for ablating tissue when electrical energy is supplied to the electrodes from the source; and

wherein the sensor array is configured to measure a spectral profile of at least one portion of the tissue site.

5. (Amended) The apparatus of claim [4]1, wherein the at least one portion includes a first portion and a second portion, the sensor array being configured to substantially simultaneously measure a first spectral profile or the first portion and a second spectral profile of the second portion.

6. (Amended) The apparatus of claim 1, further comprising:

logic resources coupled to one of the sensor array, or the sensor[, the energy delivery device or a power source coupled to the energy delivery device, the logic resources including a processor,]; and

wherein the logic resources are configured to identify or differentiate tissue responsive to a signal from one of the sensor or the sensor array.

7. (Amended) The apparatus of claim 6, wherein the logic resources are configured to distinguish between normal and abnormal tissue, wherein the abnormal tissue including at least one of abnormally mutated tissue, abnormally dividing tissue, cancerous tissue, metastatic tissue, immortal tissue or hypoxic tissue.

10. (Amended) The apparatus of claim 9, wherein the logic resources are configured to signal to one of a monitoring device or a display device the position of the energy delivery device relative to the tumor mass or to the ablation volume.

11. (Amended) The apparatus of claim 10, wherein the logic resources are configured to interface with the display device to graphically display [on the display device] the position of the energy delivery device relative to the tumor mass or the ablation volume.

12. (Amended) The apparatus of claim 6, wherein the logic resources are configured to identify a clinical endpoint for a tissue ablation procedure [of the target tissue volume].

14. (Amended) A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members each having a tissue piercing distal portion, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including [at least one of] a sensor[, a tissue piercing distal end or a lumen], the sensor array having a geometric configuration adapted to volumetrically sample and measure a spectral profile of at least one portion of a tissue site to differentiate or identify tissue at the tissue site; and

at least some of said resilient members being electrodes which can be coupled to an RF energy source for ablating tissue when electrical energy is supplied to the electrodes from the source; and.

22. (Amended) The apparatus of claim 1, wherein the sensor comprises at least one of a light conducting member or an optical fiber positionable within [the]a lumen of at least one of the [at least one]plurality of resilient members, wherein the light conducting member or the optical fiber is configured to be coupled to a light source or a coherent light source.

31. (Amended) The apparatus of claim 1, wherein the sensor array is configured to detect [at] an indicator of cell necrosis.

32. (Twice Amended) The apparatus of claim 31, wherein the indicator of cell necrosis is selected from the group consisting of a tissue vapor bubble, a rate of tissue vapor bubble formation, a denatured tissue protein, a denatured DNA [or]and an intracellular fluid.

42. (Amended) [The apparatus of claim 38,]A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members each having a tissue piercing distal portion, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including a sensor, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site or identify tissue at a tissue site;

at least some of said resilient members being electrodes which can be coupled to an RF energy source for ablating tissue when electrical energy is supplied to the electrodes from the source;

wherein the sensor includes a first sensor and a second sensor; and

wherein at least [some]one of the first or the second sensors is selected from the group consisting of an emitter, an electromagnetic emitter, an optical emitter, an acoustical emitter, a laser [or]and an LED.

50. (Amended) The apparatus of claim 1, further comprising:

at least one of (i) the elongated delivery device or (ii) at least one of the plurality of the plurality of resilient members being adapted for fluid delivery therethrough to an infusion port disposed on at least [coupled to] one of the elongated delivery device or at least one resilient member of the plurality of resilient members.

52. (Amended) [The apparatus of claim 1,]A tissue biopsy and treatment apparatus for detecting and treating tumors, the apparatus comprising:

an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue;

a sensor array deployable from the elongated delivery device, the sensor array including a plurality of resilient members each having a tissue piercing distal portion, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including a sensor, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site or identify tissue at a tissue site;

at least some of said resilient members being electrodes which can be coupled to an RF energy source for ablating tissue when electrical energy is supplied to the electrodes from the source; and

wherein the sensor array is configured to detect a marking agent.

56. (Amended) The apparatus of claim 55, wherein the marking agent is [one]selected from the group consisting of an optical marker, a fluorescent marker, a radioactive-marker, a temperature sensitive marker, an antibody, a liposome, an antibody-coated liposome, a microsphere [or]and a chemotherapeutic agent.

57. (Amended) The apparatus of claim 55, wherein the marking agent is reactive to a delivery of energy [from at least one of the energy delivery device, the sensor or the sensor array].

64. (Amended) The apparatus of claim 62, wherein at least one of the first or second tissue conditions is [one]selected from the group consisting of a thermal injury condition, a tissue necrosis, a tissue ablation, a tissue vaporization, a tissue coagulation, [or]and a cell membrane rupture.

67. (Twice Amended) The apparatus of claim 66, wherein the second tissue temperature is [one]selected from the group consisting of a tissue injuring temperature, a tissue necrosing temperature, a tissue ablative temperature, [or]and a tissue vaporization temperature.

79. (Amended) The apparatus of claim [77]1, further comprising:

a handpiece coupled to one of the elongated delivery device or the sensor array; and

a first advancement device at least partially positionable in one of the handpiece or the elongated delivery device, the advancement device being configured to advance at least one of the plurality of resilient members[or the sensor].

80. (Amended) The apparatus of claim 79, further comprising:

a second advancement device at least partially positionable in one of the handpiece or the elongated delivery device, the second advancement device configured to advance a second resilient member of the at least one [of the] plurality of resilient members [or the sensor] independent of an advancement of the first advancement device.